Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Rhone-Poulenc, Inc., 500 Northridge Rd., suite 620, Atlanta, GA 30350, filed supplemental NADA 39–417, which provides for use of Deccox® (decoquinate) Type A medicated article to make a Type C medicated feed for young sheep for the prevention of coccidiosis caused by *Eimeria bakuensis*, *E. crandallis*, *E. ovinoidalis*, and *E. parva*.

The supplemental NADA is approved as of August 28, 1995, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 28, 1995, because the supplemental NADA contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to the use for which the supplemental NADA is approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.195 is amended in paragraph (d) in the table by numerically adding a new entry to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
13.6 (0.0015 pct)		Young sheep; for the prevention of coccidiosis caused by *Eimeria ovinoidalis*, *E. crandallis*, *E. parva*, *E. bakuensis*.	Feed Type C feed at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food.	011526
*	*	*	*	*

Dated: October 5, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–25623 Filed 10–16–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 573

[Docket No. 86F–0060]

Food Additives Permitted In Feed and Drinking Water of Animals; Selenium

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for comment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal food additive regulations concerning the approved use of selenium as a food additive to suspend those amendments resulting from promulgation of a September 13, 1993, stay. This suspension conforms to certain provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1994, and the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. This interim rule amends the selenium food additive regulation to provide for the conditions set forth in these laws.

DATES: This interim regulation is effective October 17, 1995. Submit written comments by January 16, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION:

I. Background

A. 1987 Amendments

In the Federal Register of April 6, 1987 (52 FR 10887), and corrected on June 4, 1987 (52 FR 21001), FDA issued a final rule amending the selenium food additive regulation (21 CFR 573.920) to increase the maximum amount of selenium supplementation permitted in animal feeds. The action was based on

a food additive petition (FAP 2201) filed by the American Feed Industry Association, Inc. (AFIA), 1701 North Fort Myer Dr., Arlington, VA 22209. In issuing the 1987 amendments FDA determined, based on an environmental impact analysis report submitted by AFIA, that the amended uses would not have a significant impact on the human environment.

B. 1993 Stay of 1987 Amendments

In the Federal Register of September 13, 1993 (58 FR 47962), FDA published a final rule which provided for a stay of the 1987 amendments to the selenium food additive regulations (hereinafter referred to as the 1993 final rule). The action was taken in part in response to objections to, and requests for a hearing on or a stay of the 1987 amendments by a number of organizations because of alleged inadequacies found in FDA's finding of no significant impact and in the petitioner's environmental assessment. FDA concluded that the finding and the assessment were inadequate and that there was no genuine or substantial issue of fact as to their inadequacy. FDA has also concluded that the information that was available, if accepted as accurate, would not be sufficient to permit an adequate environmental analysis, and that the information that was necessary to do an adequate environmental analysis was unavailable. As a result of the stay of the 1987 amendments, the maximum permitted use levels of selenium in animal feeds returned to those levels permitted before FDA issued the 1987 amendments. FDA also stayed a 1989 amendment (54 FR 14214, April 10, 1989), to the regulation that provided for the use of a bolus for selenium supplementation at the increased levels, because the environmental assessment for the use of the bolus relied on the 1987 environmental analysis.

II. Current Status

The 103d Congress passed two laws affecting selenium supplementation of animal food. The first, signed on September 30, 1994, was included in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1994 (Pub. L. 103–330). Specifically, Title VI provided for suspension of the stay published in the 1993 final rule of the 1987 food additive regulation relating to selenium (§ 573.920) (21 CFR 573.920)) until December 31, 1995.

The second law was signed on October 13, 1994, as a part of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Pub. L. 103–354). The law, under Subtitle G—Food Safety Section 262, titled ''Conditions For Implementation of Alteration in the Level of Additives Allowed in Animal Diets,'' prohibits the implementation or enforcement of the 1993 final rule that stayed the 1987 amendments unless certain determinations are made by the Commissioner of Food and Drugs. Specifically, the determinations are set out as:

(1) Selenium additives are not essential at levels authorized in the absence of such final rule, to maintain animal nutrition and protect animal health;

(2) selenium at such levels is not safe to the animals consuming the additive;

(3) selenium at such levels is not safe to individuals consuming edible portions of animals that receive the additive;

(4) selenium at such levels does not achieve its intended effect of promoting normal growth and reproduction of livestock and poultry; and

(5) the manufacture and use of selenium at such levels cannot reasonably be controlled by adherence to current good manufacturing practice requirements.

Both laws provide for suspension of FDA's 1993 stay until certain conditions are met. Pub. L. 103–330 provides for a suspension until December 31, 1995, and Pub. L. 103–354 provides for a suspension until certain determinations are made by the Commissioner of Food and Drugs. Therefore, selenium may be administered in animal feed as sodium selenite or sodium selenate in the complete feed for chickens, swine, turkeys, sheep, cattle, and ducks as provided for by the 1987 amendments to § 573.920, until further notice. The published regulation provides for the currently acceptable levels of selenium supplementation of feed; that is, levels not to exceed 0.3 parts per million (ppm) in feed supplementation of chickens, swine, turkeys, sheep, cattle, and ducks; in feed supplements for sheep not to exceed 0.7 milligram (mg) per head per day and in beef cattle not to exceed 3 mg per head per day; and in free-choice salt-mineral mixes for sheep up to 90 ppm but not to exceed 0.7 mg per head per day and for beef cattle up to 120 ppm in a mixture for free-choice feeding not to exceed an intake of 3 mg per head per day. In addition, the orally administered, osmotically controlled, and constant release bolus for beef and dairy cattle provided for on April 10, 1989 (54 FR 14214), is also available until further notice.

III. Authority for This Regulation

Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B) and FDA's administrative practices and procedures regulation at 21 CFR 10.40(e), the Commissioner finds for good cause that prior notice and comment on this interim rule are unnecessary. The rule does not involve any exercise of discretion by the Commissioner. It merely repeats the terms of Pub. L. 103–354. As provided in FDA's administrative practices and procedures regulation at 21 CFR 10.40(e), FDA is providing an opportunity for public comment on whether the interim rule should be modified or revoked.

IV. Request for Comments

Interested persons may, on or before January 16, 1996, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 573.920 is amended by redesignating the introductory text and paragraphs (a) through (f) as paragraphs (a) through (g) respectively, and by revising newly redesignated paragraph (a) to read as follows:

§ 573.920 Selenium.

(a) Public Law 103–354 enacted October 13, 1994 (the 1994 Act), states that FDA shall not implement or enforce the final rule issued on September 13, 1993 (58 FR 47962), in which FDA stayed the 1987 amendments and any modification of such rule issued after enactment of the 1994 Act; unless the Commissioner of Food and Drugs makes a determination that:

(1) Selenium additives are not essential at levels authorized in the absence of such final rule, to maintain animal nutrition and protect animal health;

(2) selenium at such levels is not safe to the animals consuming the additive;

(3) selenium at such levels is not safe to individuals consuming edible portions of animals that receive the additive;

(4) selenium at such levels does not achieve its intended effect of promoting normal growth and reproduction of livestock and poultry; and

(5) the manufacture and use of selenium at such levels cannot reasonably be controlled by adherence to current good manufacturing practice requirements.

(6) Paragraphs (b) through (g) of this section provide the currently acceptable levels of selenium supplementation.

* * * * *

Dated: October 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–25622 Filed 10–16–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 223

Sale and Disposal of National Forest System Timber; Administration of Timber Export and Substitution Restrictions

AGENCY: Forest Service, USDA.

ACTION: Final rule; suspension of compliance and reopening of comment period.

SUMMARY: On September 8, 1995, the final rule for Sale and Disposal of National Forest System Timber—Administration of Timber Export and Substitution Restrictions was published in the Federal Register with request for additional comment on any functioning of the regulation that may be necessary for more efficient implementation (60 FR 46890). The rule was effective September 8, 1995, and the comment period was specified to close October 10, 1995. The Department has decided to suspend compliance with 36 CFR 223.190(k) and 223.193 through 223.199 of the final rule until February 14, 1996. This action will provide time for a more orderly and planned implementation by the forest products industry and the Forest Service. During this suspension period, all other provisions of the final rule remain in effect and provisions of the timber sale contract relating to these matters will remain in effect. In addition, the comment period is hereby reopened until December 18, 1995.

DATES: The suspension of compliance with 36 CFR 223.190(k) and 223.193 through 223.199 of the final rule published at 60 FR 46922 is effective September 8, 1995, through February 14, 1996. Comments on the final rule must be received in writing by December 18, 1995.

ADDRESSES: Send written comments to Director, Timber Management Staff (2400), Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090.

The public may inspect comments received on this final rule in the Office of the Director, Timber Management Staff, Forest Service, USDA, Wing 3NW, Auditors Building, 201 14th Street, SW., Washington, DC 20250, between the hours of 8:30 a.m. and 4:30 p.m. Parties wishing to view comments are encouraged to call ahead (202–205–0893) to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Rex Baumback, Timber Management Staff, Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090, (202) 205–0855.

Dated: October 10, 1995.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 95–25653 Filed 10–16–95; 8:45 am]

BILLING CODE 3410–11–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–5315–1]

Louisiana: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The State of Louisiana has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed Louisiana's application and determined that its hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Unless adverse written comments are received during the review and comment period provided for public participation in this process, EPA intends to approve Louisiana's hazardous waste program revision subject to the authority retained by EPA in accordance with Hazardous and Solid Waste Amendments of 1984. Louisiana's application for the program revision is available for public review and comment.

DATES: This authorization for Louisiana shall be effective January 2, 1996, unless EPA publishes a prior Federal Register (FR) action withdrawing this immediate final rule. All comments on Louisiana's program revision application must be received by the close of business December 1, 1995.

ADDRESSES: Copies of the Louisiana program revision application and the materials which EPA used in evaluating the revision are available for inspection and copying from 8:30 a.m. to 4 p.m., Monday through Friday at the following addresses: Louisiana Department of Environmental Quality, H.B. Garlock Building, 7290 Bluebonnet, Baton Rouge, Louisiana 70810, phone (504) 765–0617 and U.S. EPA, Region 6 Library, 12th Floor, First Interstate Bank Tower at Fountain Place, 1445 Ross Avenue, Dallas, Texas 75202–2733, phone (214) 665–6444. Written comments, referring to Docket Number LA–95–4, should be sent to Alima Patterson, Region 6 Authorization Coordinator, Grants and Authorization Section (6PD–G), U.S. EPA Region 6, First Interstate Bank Tower at Fountain Place, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8533.

FOR FURTHER INFORMATION CONTACT: Alima Patterson, Region 6 Authorization Coordinator, Grants and Authorization Section (6PD–G), U.S. EPA Region 6, First Interstate Bank Tower at Fountain Place, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8533.

SUPPLEMENTARY INFORMATION:

A. Background

States authorized under section 3006(b) of the Resource Conservation and Recovery Act (''RCRA or the Act''), 42 U.S.C. 6926(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR parts 124, 260–268, and 270.